IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ Application of Kenneth Iain Cumming and
Zebunnissa Ramtoola
Application No. 09/510,560 Examiner: J. Lundgren
Filed February 22, 2000 Art Unit 1615
Confirmation No. 3011

SOLID ORAL DOSAGE FORM CONTAINING AN ENHANCER

(Attorney Docket No. P24,375-A USA)

FILED ELECTRONICALLY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW OF MARCH 7, 2007

Sir:

Applicants hereby submit this statement setting forth the substance of the interview that was conducted on March 7, 2007 in connection with the above-captioned application. This statement is filed in accordance with the requirements of 37 C.F.R. § 1.133 and MPEP 713.04, and in response to the Interview Summary, mailed March 12, 2007, having a non-extendible period for reply set to expire on April 12, 2007.

On March 7, 2007, in interview in the above-captioned application was convened. In attendance were Examiner Jeffrey S. Lundgren, Dr. Thomas W. Leonard, Chief Scientific Officer of the assignee of the application, and its counsel (the undersigned). The interview began promptly at 10:00 am, and ran for about an hour.

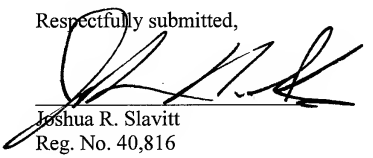
The interview began with applicants presenting an overview of technology developments in the fields of dosage forms and absorption enhancers. This review included a discussion of the common path of developmental evolution in dosage forms from liquids to solids, and the generally accepted preference for solids over liquids in both dosage forms and enhancer systems. Applicants also discussed microemulsion (i.e., surfactant) enhancer systems for use in the oral administration of poorly absorbable drugs. This discussion was accompanied by a PowerPoint presentation (in spiral-bound paper form) highlighting the discussion points. A copy of the presentation made at the interview is submitted herewith.

Following this overview, there was a discussion of the most recently cited references, namely, Bachynsky et al., Irish Patent No. (11) 63119, Bachynsky et al., U.S. Patent No. 5,190,748, Fujii et al., U.S. Patent No. 5,840,685, and Watts et al., WO 97/05903. In this discussion, applicants highlighted the teachings in these references of the use of surfactants in combination with medium chain fatty acids as examples of developments in microemulsion enhancer systems of the prior art. During the discussion of specific compositions taught in these cited references, the Examiner was provided with vials containing samples of the constituent materials recited in such compositions. These samples of constituent materials included sodium caprate, capric acid, Labrasol, Laureth-12, and insulin.

The interview then addressed the present invention as now claimed. While all of the claims were addressed, the discussion was focused on the independent claims, namely, claims 178, 211, 240, 246 and 252. After describing generally the innovation represented by the present invention, the discussion turned to particular claim elements common to all of the independent claims. Specifically, the discussion centered on the enhancer being defined as: (1) a salt of a medium chain fatty acid (within the stated carbon chain length range); and (2) the only enhancer present in the composition or dosage form. In highlighting these common claim elements, as well as the compressibility of the composition in the composition claims, the discussion returned to the teachings of the cited references and how the claimed features of the present invention are found nowhere therein.

At the conclusion of the interview, the Examiner advised that examination of the pending claims would be taken up in an order consistent with applications of similar pendency, and that a further Office Action would be issued shortly thereafter.

Respectfully submitted,



Joshua R. Slavitt
Reg. No. 40,816

Synnestvedt & Lechner LLP
2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950
Telephone - (215) 923-4466
Facsimile - (215) 923-2189